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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,961	02/02/2004	Hans-Dietrich Polaschegg	POLA-01	9120

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EXAMINER
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ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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01/21/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/769,961	<b>Applicant(s)</b> POLASCHEGG, HANS-DIETRICH	
	<b>Examiner</b> JAMES W. ROGERS	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9-20 is/are pending in the application.
- 4a) Of the above claim(s) 9-10,16-18 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,11-15 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/17/2008 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,3-4,11-12 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Paradies (US 4,870,174).

Paradies teaches alginate thixotropic gels dispersed in water, the gels contained antiviral substances. See examples 2 and 9. Regarding applicants limitations within steps i)-iii) that the composition can be injected into a hemodialysis catheter and how

Art Unit: 1618

the composition advances through the lumen, these intended use type of limitations are considered met by the examiner because since the compositions are the same they will inherently be able to perform the same intended use even if this feature is not disclosed within Paradies. The subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined. As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation. Regarding the limitation of claim 4 that the composition is a microgel, since applicants have not defined the meaning of microgel within their specification the examiner interpreted this limitation with the broadest reasonable interpretation. The examiner defined microgel to simply be any gel that contains crosslinked polymers that are microscopic are smaller, since the hydrogel of Paradies contains polymers that are crosslinked the limitation is considered met by the Paradies patent.

Claims 1,3-4,11-15 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Short et al. (US 5,578,119).

Short teaches a sculpting medium comprising a thixotropic hydrogel binder including sodium alginate or sodium carboxymethylcellulose and polymeric microspheres. See claims. A desirable additive to the medium was an antimicrobial agent. The intended use claims are treated the same as in the above Paradies patent.

Claims 1,3-4,7 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Eini et al. (US 2004/0253275 A1).

Eini teaches pharmaceutical and cosmetic carriers that contain antimicrobial agents, analgesics including salicylic acid, the carrier could be in the form of a thixotropic gel formulation. See [0061],[0062][0075],[0084],[0132] and [0188]. The intended use claims are treated the same as in the above Paradies patent.

Claims 1,3-4,6,13 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (US 2003/0157178 A1).

Chen teaches injectable depot compositions that are thixotropic gels produced from polylactide, the gels could further contain anticoagulants and antibiotic agents. See abstract, [0020],[0055] and [0056]. The intended use claims are treated the same as in the above Paradies patent.

Claims 1,3-5,11,13-15 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Luissi et al. (US 4,587,284), for the reasons set forth in the previous office actions filed 09/12/2007 and 05/14/2008.

Claims 1,3-4,6,13-15 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Marchant et al. (US 6,297,337 B1), for the reasons set forth in the previous office actions filed 09/12/2007 and 05/14/2008.

Claims 1,3-5,11-15 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Wokalek et al. (US 4,905,700), for the reasons set forth in the previous office actions filed 09/12/2007 and 05/14/2008.

Claims 1,3,7,11-15 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Young et al. (US 2003/0180347 A1), for the reasons set forth in the previous office actions filed 09/12/2007 and 05/14/2008.

Claims 1,3-5 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by PFIRRMANN et al. (WO 94/03174), for the reasons set forth in the previous office action filed 09/12/2007 and 05/14/2008.

### ***Response to Arguments***

Applicant's arguments filed 11/17/2008 have been fully considered but they are not persuasive.

Applicants assert that none of the cited references relates to a thixotropic gel having the characteristics called for in claim 1 thus none of the references teaches a composition similar to applicants claimed invention.

The examiner respectfully disagrees with the above assertion. The intended use type of limitations within steps (i)-(iii) of claim 1 are considered met by the prior art because the compositions are within applicants claimed scope thus they will inherently be able to perform the same intended use even if this feature is not disclosed within the references. Applicants have not amended their claims in such a way as to preclude the prior art references since applicants composition does not limit the ingredients or the

Art Unit: 1618

amounts of those ingredients so that the prior art does not anticipate their claims. The subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined. As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation. As recited previously since the references above all teach a composition within applicants claimed scope it is assumed that the same composition will have the same properties. It appears as though applicants may be attempting to claim a new property of an old composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Applicants also assert that since Luissi teaches hydrophilic gels they would swell as they absorbed water in the blood if delivered by catheter and this swelling would render the catheter unusable or the polymer would flow out into the blood stream. Applicants further assert that Wokalek describes a hydrogel as a uniform parallel-sided sheet that would have high yield strength and high viscosity if flowing, thus the composition could not be a thixotropic gel. Applicant's further state that Young teaches

Art Unit: 1618

an adhesive patch and applicants do not believe that Young teaches their thixotropic gel. Applicants also assert that Pfirmann teaches a liquid gel that would have a high viscosity and would render it undesirable for use as a catheter lock solution. Lastly applicants assert that they believe even at the lowest viscosity described within the Pfirmann reference it would be too viscous for use as a syringe-delivered catheter lock.

Firstly the examiner notes that the arguments by applicants above are conclusionary in nature as to the assertions that the properties of the gels taught in the references have undesirable properties for a catheter lock solution. Applicants have not provided experimental evidence that the gels described in the references above would not be capable of providing the same intended use as claimed. The examiner can only search for what is claimed, currently in order to meet applicants claims the gel must contain an antimicrobial and from dependent claims 11-15 a polymer selected from a natural or synthetic polymer. As long as the composition is within applicants claimed scope it is inherent that any property of that composition will necessarily also be the same. Applicants have simply not limited the breadth of their claims to remove the prior art rejections above since the examiner must assume that the same composition containing the same ingredients will also have the same properties.

### **Conclusion**

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.



Art Unit: 1618

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618